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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,889	01/13/2004	Steven G. Nadler	D0284 NP	1732

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,889	NADLER ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-359, claim(s) 1-5, in part, drawn to a nucleic acid corresponding to one of 359 sequences, classified in class 536, subclass 23.1. Each of groups 1-359 corresponds to a single SEQ ID NO: set forth in the claim, of which there are 359. For example, if applicant elects group 1, claims 1-5 will be searched and examined with respect to SEQ ID NO: 1. If applicant elects group 2, claims 1-5 will be searched and examined with regard to SEQ ID NO: 3.

Groups 360-718, claim(s) 6-7, in part, drawn to a polypeptide corresponding to one of 359 sequences, classified in class 530, subclass 350. Each of groups 360-718 corresponds to a single SEQ ID NO: set forth in the claim, of which there are 359. For example, if applicant elects group 360, claims 6-7 will be searched and examined with regard to SEQ ID NO: 2.

Groups 719-1077, claim(s) 8, in part, drawn to an antibody which binds to a polypeptide of claim 6, classified in class 530, subclass 387.1 Each of groups 719-1077 corresponds to a single SEQ ID NO: set forth in claim 6, of which there are 359. For example, if applicant elects group 719, claim 8 will be searched and examined with regard to an antibody which binds to SEQ ID NO: 2.

Groups 1078-1436, claim(s) 9, in part, drawn to a method of treatment with a polypeptide of claim 6, classified in class 514, subclass 2. Each of groups 1078-1436 corresponds to a single SEQ ID NO: set forth in claim 6, of which there are 359.

Groups 1437-1795, claim(s) 10, in part, drawn to methods of diagnosis with a polynucleotide of claim 1, classified in class 435, subclass 6. Each of groups 1437-1795 corresponds to a single SEQ ID NO: set forth in claim 1, of which there are 359.

Groups 1796-2154, claim(s) 11, in part, drawn to methods of diagnosis with a polypeptide of claim 6, classified in class 435, subclass 7.1. Each of groups 1796-2154 corresponds to a single SEQ ID NO: set forth in claim 6, of which there are 359.

Groups 2155-2513, claim(s) 12, in part, drawn to a method of identifying a binding partner of a polypeptide of claim 6, classified in class 435, subclass 7.1 Each of groups 2155-2513 corresponds to a single SEQ ID NO: set forth in claim 6, of which there are 359.

Groups 2514-2872, claim(s) 13, in part, drawn to a method of treatment with a modulator of one of 359 polypeptides, classified in class 514, subclass 1.

Groups 2873-3231, claim(s) 14-15, in part, drawn to a method of identifying a compound that modulates the activity of one of 359 polypeptides, classified in class 436, subclass 536.

Groups 3232-3590, claim(s) 16-17, in part, drawn to a method of identifying a compound that modulates the activity of one of 359 nucleic acids, classified in class 536, subclass 24.5.

Group 3591-4308, claim(s) 18, in part, drawn to a modulator identified by either the methods of claims 14 and 15 or 16 and 17. As no structure is given, the examiner in unable to properly classify this claim.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups 1-359, 360-718, 719-1077, and 3591-4308 are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acids of group 1-359 are composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptides of groups 360-718 are composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibodies of groups 719-1077 are also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The modulators of groups 3591-4308 can be any molecule such as nucleic acids, peptides, antibodies, small non peptide organic compounds, etc. The products of groups 1-1077 and 3591-4308 can be used in materially different processes, for example the nucleic acids can be used in hybridization assays, the antibodies can be used in immunoassays, the polypeptides can be used to make a fusion protein with an enzymatic function, and the modulators can be used to alter activity of a molecule. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups 1-1077 and 3591-4308 are patentably distinct from each other. The search for each of the groups presents a serious search burden as the searches for

each are not coextensive in scope. The inventions have different status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies. Furthermore, antibodies which bind to an epitope of a polypeptide of group may be known even if the polypeptide is novel. Art relating to a nucleic acid or protein would not necessarily provide any information regarding molecules which would inhibit their function. Searching, therefore is not coextensive.

The inventions of groups 1-359 and 719-1077 are unrelated to the inventions of groups 1078-1436, 1796-2154, 2155-2513, 2514-2872, and 2873-3231. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. The products of groups 1-359 and 719-1077 are not used in the methods of groups 1078-1436, 1796-2154, 2155-2513, 2514-2872, and 2873-3231.

The inventions of groups 360-718 and 719-1077 are unrelated to the inventions of groups 1437-1795 and 3232-3590. Inventions are unrelated if it can be shown that they are not

disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. The products of groups 360-718 and 719-1077 are not used in the methods of groups 1437-1795 and 3232-3590.

The inventions of groups 1078-1436, 1437-1795, 1796-2154, 2155-2513, 2514-2872, 2873-3231, and 3232-3590 are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. The methods of diagnosis have different modes of operation with respect to each other as they involve different reagents and reaction parameters. The methods of treatment have different modes of operation with respect to each other as they involve different reagents and reaction parameters. The methods of screening have different modes of operation with respect to each other as they involve different reagents and reaction parameters. Additionally, the methods of diagnosis, treatment, and screening have different modes of operation, different effects, and different functions with respect to each other.

The inventions of each of groups 1-359, each of groups 360-718, each of groups 19-1077, each of groups 1078-1436, each of groups 1437-1795, each of groups 1796-2154, each of groups 2155-2513, each of groups 2514-2872, each of groups 2873-3231, each of groups 3232-3590, and each of groups 3591-4308 are patentably distinct from each other as each group is drawn to a structurally and functionally distinct molecule. Nucleotide sequences encoding

different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

The inventions of group 1-359 and groups 1437-1795 & 3232-3590 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used to express proteins which are not required for the methods of groups 1437-1795, or as to make probes and primers, which is not required for the methods of groups 3232-3590. Art relating to structural limitations of nucleic acids will not necessarily provide any information relating diagnosis of disease or to modulators of the nucleic acid, and vice versa. Accordingly, a

serious burden exists for searching more than one of the patentably distinct groups as the searches are not coextensive.

The inventions of groups 360-718 and groups 1078-1436, 1796-2154, 2155-2513, & 2873-3231 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins can be used to make fusion peptides with enzymatic function the methods of groups 1437-1795, or as to make probes and primers, which is not required for the methods of groups 1078-1436, 1796-2154, 2155-2513, & 2873-3231. Art relating to structural limitations of a protein will not necessarily provide any information relating diagnosis of disease, treatment of disease, or identification of molecules that would bind to or inhibit the activity of the polypeptide, and vice versa. Accordingly, a serious burden exists for searching more than one of the patentably distinct groups as the searches are not coextensive.

The inventions of groups 3591-4308 and 2873-3231 & 3232-3590 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the modulators can be made using chemical means. Art relating to structural characteristics of the modulators will not necessarily provide any information regarding the actual modulating activity of the products, and vice versa.

Accordingly, a serious burden exists for searching more than one of the patentably distinct groups as the searches are not coextensive.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for each group is not required for any other group, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-

0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634
9/29/05